MEDICINES AND VACCINE SAFETY

A beginner's guide to pharmacovigilance

Uppsala Monitoring Centre

Pharmacovigilance is about detecting, understanding, and preventing side effects of medicines and vaccines

Medicines and vaccines and their effects

While medicines and vaccines are generally beneficial to most people, they can sometimes cause discomfort – such as headaches, rashes, or tiredness. These are known as side effects or adverse reactions. In rare cases, adverse reactions may be severe or even fatal. When considering a medicine or vaccine, the patient and doctor must weigh the benefits against the potential risks of discomfort or harm.

How medicines cause harm

Medicines and vaccines can affect people in different ways. Clinical trials provide some safety information, but other effects may only emerge as more people use them over time. Sometimes, rare side effects only become apparent after a large number of people have taken the medicine or vaccine. Reporting these rare side effects is important to help keep these products safe.

Reducing the risk of harm

To use medicines and vaccines safely, it's important to follow medical advice and be aware of any unexpected or negative effects. Taking medicines as directed, completing the full course, and avoiding interactions with alcohol, some foods, or other medications helps to reduce the risk of harm. For vaccines, following the recommended schedule and completing all necessary doses is crucial.

However, the risk of side effects can't be completely eliminated. Understanding possible side effects and knowing how to deal with them if they occur means you're more likely to get the care you need. The first step is usually to report the problem to a healthcare provider.

Telling your healthcare provider about side effects will help everyone use medicines and vaccines in a safer way

Keeping an eye on medicines safety

Recognising and reporting side effects helps make medical treatments safer and more effective, and can prevent harm to others. Side effects can be reported either to a healthcare provider, such as a doctor or pharmacist, the manufacturer, or directly to the regulatory authority. These adverse event reports are collected in a national database and used to identify patterns between a medicine or vaccine and reported side effects. If a pattern suggests a wider problem, it can lead to regulatory actions – such as changes to product labelling, guidance on when and how the medicine or vaccine should be used, or even withdrawal from the market.

National authorities are encouraged to share their reports with VigiBase, the WHO global database of adverse event reports for medicines and vaccines. Maintained by UMC, VigiBase contains millions of reports from around the world, helping to identify safety issues that may not be immediately apparent from national data alone.

Building a global picture of medicines and vaccine safety

VigiBase is a global database created for members of the WHO Programme for International Drug Monitoring (WHO PIDM). Maintained by UMC, it helps them find and share safety concerns about medicines and vaccines. Today, national authorities in more than 180 WHO member states, territories, and areas – covering 99% of the world's population – contribute reports to VigiBase.

Why do we need a global database?

Side effects can happen anywhere, at any time. Collecting safety data from around the world helps alert WHO PIDM members to issues that may not be apparent from their own national data. This helps them to identify rare side effects early.

Who can access VigiBase data?

Certain staff at WHO PIDM member organisations and other organisations working with medicines and vaccine safety can access the data subject to strict data access conditions.

Where do reports come from?

Reports are submitted to national authorities by healthcare professionals, the public, and pharmaceutical companies. These are first checked and analysed locally – sometimes leading to regulatory action – and then shared with VigiBase.

Does a report in VigiBase mean a confirmed side effect?

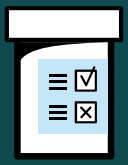
No, a report does not confirm a side effect. When someone feels unwell after taking a medicine or receiving a vaccine, it doesn't necessarily mean that the medicine or vaccine caused it. Every report helps pharmacovigilance professionals track potential issues, but further investigation is needed to determine if the medicine or vaccine is the cause.

Why is VigiBase managed by UMC?

The database moved to Sweden in 1978, and UMC has maintained it since then as a WHO Collaborating Centre for International Drug Monitoring. As VigiBase has grown to tens of millions of reports, UMC has developed methods and tools to make the data easier to search and analyse.

How medicines safety works

Follow Lisa's journey through the different stages of the medicines safety cycle



This is Lisa ...

Lisa is 55 years old and has type 2 diabetes. Her recent laboratory results indicate that her blood glucose levels are no longer controlled by diet and the medicine she has been taking.

Treat

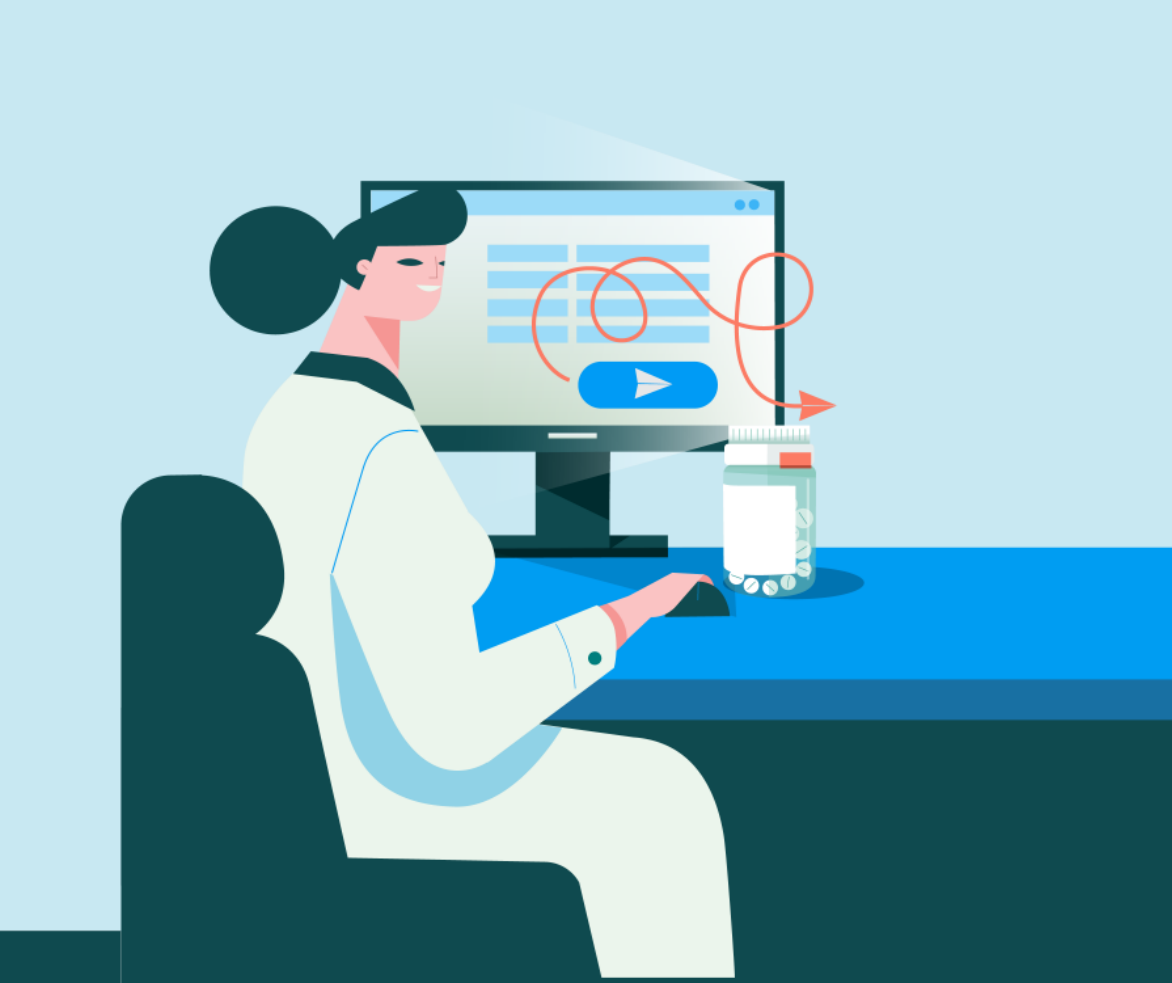
Lisa's doctor prescribes her Loglutin, a new medicine that has just come on the market. Lisa collects the medicine from her local pharmacy. The pharmacist informs her of the known potential side effects: headache, muscle pain and rash.

After a week, Lisa develops abdominal pain and nausea.
A few days later she notices her skin is turning yellow.
She wonders if it has something to do with her new medicine.
She makes an appointment with her doctor to find out.

Recognise

Lisa's doctor does blood tests, which confirm her suspicion that Lisa has developed hepatitis (inflammation of the liver). She checks that Lisa is not taking any other medications that could be the cause of the hepatitis. She also orders more tests to confirm that there are no other possible causes, such as viral infections or cancer. She advises Lisa to stop taking Loglutin.

Over the next two weeks, Lisa experiences no abdominal pain or nausea, and her skin clears up. Also, her liver function tests are almost back to normal.



Report

Lisa's doctor fills out a report for the adverse event Lisa has experienced, as she suspects Loglutin may be the cause. Hepatitis was not listed as a known side effect. She sends the report to the national regulatory authority.

Collect

Lisa's case is added to the national database of adverse event reports for medicines and vaccines. Since the regulatory authority in Lisa's country is a member of the WHO Programme for International Drug Monitoring, her report is shared with the global database, VigiBase.

Analyse

At the regulatory authority, Lisa's report is reviewed by a case assessor who finds similar reports on Loglutin and hepatitis in the national database and VigiBase. In a small number of cases serious liver damage occurred.

Further analysis shows it is probable that Loglutin caused Lisa's hepatitis.

Act

The regulatory authority decides that Loglutin's manufacturer has to make changes to the label. Hepatitis is added to "Undesirable Effects" and the possible risk of serious liver problems is added to the "Warning" section.

Communicate

An advisory letter is sent to health providers, with additional information made available on the regulatory authority's website. Lisa's doctor shares the news with her.

Prevent

Lisa's report has contributed to a better understanding of Loglutin's risks. Reports can help discover new side effects and provide valuable information on managing known risks.

Lisa's doctor changes her medication to another type 2 diabetes medicine – Glucotan – from which she is experiencing no side effects.

Glossary of key terms

Adverse reaction/side effect
An unwanted or unexpected effect that is likely caused by a medicine or vaccine.

Adverse event
Any health problem that happens after using a medicine or vaccine, whether or not it is caused by the product.

Benefit–risk balance
The comparison between the positive effects of a medicine or vaccine and its potential risks.

Clinical trial
A research study carried out to test the safety, effectiveness, or both, of a medicine or vaccine before it is approved for general use.

Pharmacovigilance (PV)
The science of detecting, understanding, and preventing side effects of medicines and vaccines.

Regulatory authority
A national or regional organisation responsible for approving, monitoring, and regulating the use of medicines and vaccines.

VigiBase
The World Health Organization's global database of adverse event reports for medicines and vaccines.

WHO Programme for International Drug Monitoring (WHO PIDM)
A global network of national regulatory authorities that share safety information to improve the monitoring of medicines and vaccines.

Uppsala Monitoring Centre

Safer use of medicines and vaccines for everyone everywhere

Uppsala Monitoring Centre (UMC) is an independent, self-funded, non-profit foundation established in 1978 dedicated to safer use of medicines and vaccines. Through an agreement between the Government of Sweden and the World Health Organization (WHO), UMC operates the Programme for International Drug Monitoring, supporting over 180 member countries and regions in strengthening safety surveillance, and maintains VigiBase, the WHO global database of adverse event reports. In addition, UMC provides international standards and related digital solutions for secure exchange of pharmacovigilance data, including a global medicine and vaccine terminology for identification of medicinal products. With around 200 staff, UMC advances the science of pharmacovigilance and transforms its practice through technological innovation.

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